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TO: Board of patent appeals & Interferences.

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OF PAGES TRANSMITTED (INCLUDING THIS PAGE): 11

NOTES:

1/12/2011

United States Trademark and Patent Office

Board of Patent Appeals and Interferences

Appeal No: 2010-003194

Application No: 10/812,380 Filing Date: 3/29/2004

Attorney Docket No: 1800-000001

Confirmation No: 2606

Examiner: Leslie R Deak

Art Unit: 3761

Apellant: Iftikhar Khan, Nazir Khan, et al.

Request for Rehearing under 37CRF 41.52

The appellants file a request for a rehearing seeking reconsideration of the appeal board's decision on 8/24/2010 rejecting claim 17 under U.S.C. Section 103 in view of Squitieri, Parks, and Twardowski. The appellants request a rehearing based on the facts and the law so that the rejection be withdrawn and an opportunity given for a rehearing to discuss the issues.

1. **The Parks invention**

   Parks invention (see Fig. B). The examiner, in her response the appeal brief (page 10) described three regions (82,84, and 86) of Parks' connector where the catheters are inserted, serving as taper locks. Parks' connector goes within the inlet end of the conduit (see column 3, line 10 of

Parks' patent & see Fig. 12 of Parks' Invention). The examiner, in her response, did not mention in what direction the catheter is going to come, whether from the inlet or the outlet end. The Parks connector is designed to have a catheter on the inlet end and thus, the fluid through the catheter comes from the inlet end (see Fig. B). If Parks' connector is put in the graft of the claimed invention, it will stay close to the artery in the graft and the catheter will come from the inlet end, causing turbulence, obstructing the flow of blood, and thrombosis, rendering the invention inoperable. (In Re Gordon, 733 F. 2d 900, 221 USPQ 1125 (Fed Cir 1984)) If Parks' connector is applied to the claimed invention, there will be no outflow catheter (see Fig. B). The Parks connector is made of a hard substance, and it will be a foreign body within the arterial conduit graft, leading to thrombosis within the graft. It is a well established principal in vascular medicine that any foreign body within the arterial tree, where blood is flowing ,will cause thrombosis of the artery.

2. Twardowski's catheter (see Fig. D) is a double lumen catheter with a part coming out of the skin and has two ports outside of the skin. This catheter cannot be fitted to Squitieri's art of single lumen catheter, and therefore, the claimed invention cannot be made. Therefore the claimed invention is not obvious, under USC 35, section 103. One skilled in the art will not combine Twardowski's catheter with Squitieri's art, because the claimed invention cannot be made, and the enablement, best mode requirement under USC 35, Section 112, Paragraph 1,6 is not satisfied.

3. The examiner stated under Re Keller, 642 F. 2d 413,209 USPQ 871 (CCPA 1981) that it is not essential to combine the devices bodily. The examiner misapplied the law, without bodily combining Squitieri's and Twardowski's devices, the shunt dialysis function of the claimed

invention cannot be achieved, and it will only be Twardowski's catheter dialysis. The appeals board overlooked this fact.

4. **Secondary Considerations**

A) The results of the study are described under declaration, exhibits 1 and 2. In exhibit 1, the clinical study conducted by Katzman showed the HeRO device visa viz Twardowski's catheter is superior in the performance of the function of dialysis, reduction of infection rate, and longer patency. The superior performance of the claimed invention, as indicated by adequacy of dialysis data KT/V as 1.7, is an unexpected finding. Comparing the clinical data with Squitieri's invention there is no clinical data available, with respect to the infection rate, performance, or the patency to compare. As stated in the declaration, exhibit 2, the study carried out by Chris Stout, M.D. et al showed that the Hero device proved successful in converting catheter dependent dialysis cases into conventional arteriovenous shunt dialysis in 50 out of 52 cases with central vein occlusion. Chronic renal failure cases with central vein obstruction of the superior vena cava can only be corrected by the claimed invention, but not by Squitieri's invention because in Squitieri's art, the catheter remains in superior vena cava, and in the claimed invention, after angioplasty of central vein obstruction, the catheter will bypass the obstruction and go into the heart. This is an unexpected finding, and a great advantage of the claimed invention over Squitieri's art.

B) A long felt, unsolved problem, is the problem of neointimal hyperplasia (see Fig. C) which results from vein wall injury due to high blood flow into the vein. This problem has not been solved since Baker's creation of the arteriovenous shunt in 1976. Squitieri's invention as well as others could not solve this problem. The claimed invention is the only one that

solves the problem because the blood does not have contact with the vein wall. The catheter takes the blood directly into the right side of the heart. Vein wall injury, leading to neointimal hyperplasia, accounts for 80% of graft failure. The claimed invention will prevent this 80% of graft failure.

C) **Copying of the Invention:** Hemosphere Inc. copied the claimed invention as the HeRO device. Hemosphere Inc. realized the graft failure from neointimal hyperplasia can be solved by the claimed invention. This rebuttal evidence, makes the claimed invention nonobvious.

D) **Commercial Success:** Hemosphere Inc. presented the commercial success of the HeRO device to the Society of Vascular Surgery in June 2010 in Colorado. This Commerical success is a rebuttal evidence making the claimed invention , non obvious

5. The principal of operation of the claimed invention, Squitieri's and Twardowski's arts are different. This makes the claimed invention non-obvious because the principles of operation are different. (in Re Ratti, 270 F. 2d 810,123 USPQ 349 (CCPA 1959))

6. **Modification of Squitieri's Art**

The modification of Squitieri's invention by the examiner was only based on speculation without reasoning, because the examiner modified it without any teaching in Squitieri's art. The law is ,to modify the prior art, there must be some teaching in the prior art (MPEP 2143.01 in re Kahn, 441 F. 3d, 977, 986, 78 USPQ 2d 1329, 1335 (Fed Cir 2006)). The examiner did not demonstrate

any advantage in Squitieri's art over the claimed invention. The law requires, to modify an art, there must be some advantage (Sernacker, 702 F. 2d 989,994-5,217 USPQ 1,5-6 (Fed Cir 1983)). One skilled in the art would not modify Squitieri's art because there is no teaching suggestion or any advantage by doing so. The appeals board made an error in agreeing with the examiner.

7. The claimed invention satisfied the three Graham factors under the Supreme Court ruling. (Graham v. John Deere Co {383 US 1,148 USPO 459} 1966)

Combining the prior arts of Squitieri, Parks, and Twardowski will result in the destruction of the function of the Squitieri art and will not make the claimed invention obvious under USC 35, Sec 103. If parks connector is applied to the claimed invention it will destroy the function causing thrombosis of the graft. The unexpected results, superior performance of the claimed invention rebut prima facie obviousness.

The appellants request that a hearing be granted so that the issues can be discussed at the hearing meeting. The evidence of nonobviousness of the claimed invention outweighs the obvious evidence of the examiner. Therefore, rejection of claim 17 should be withdrawn. The appellant application is in a special status, and early decision is requested.

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Fig. A

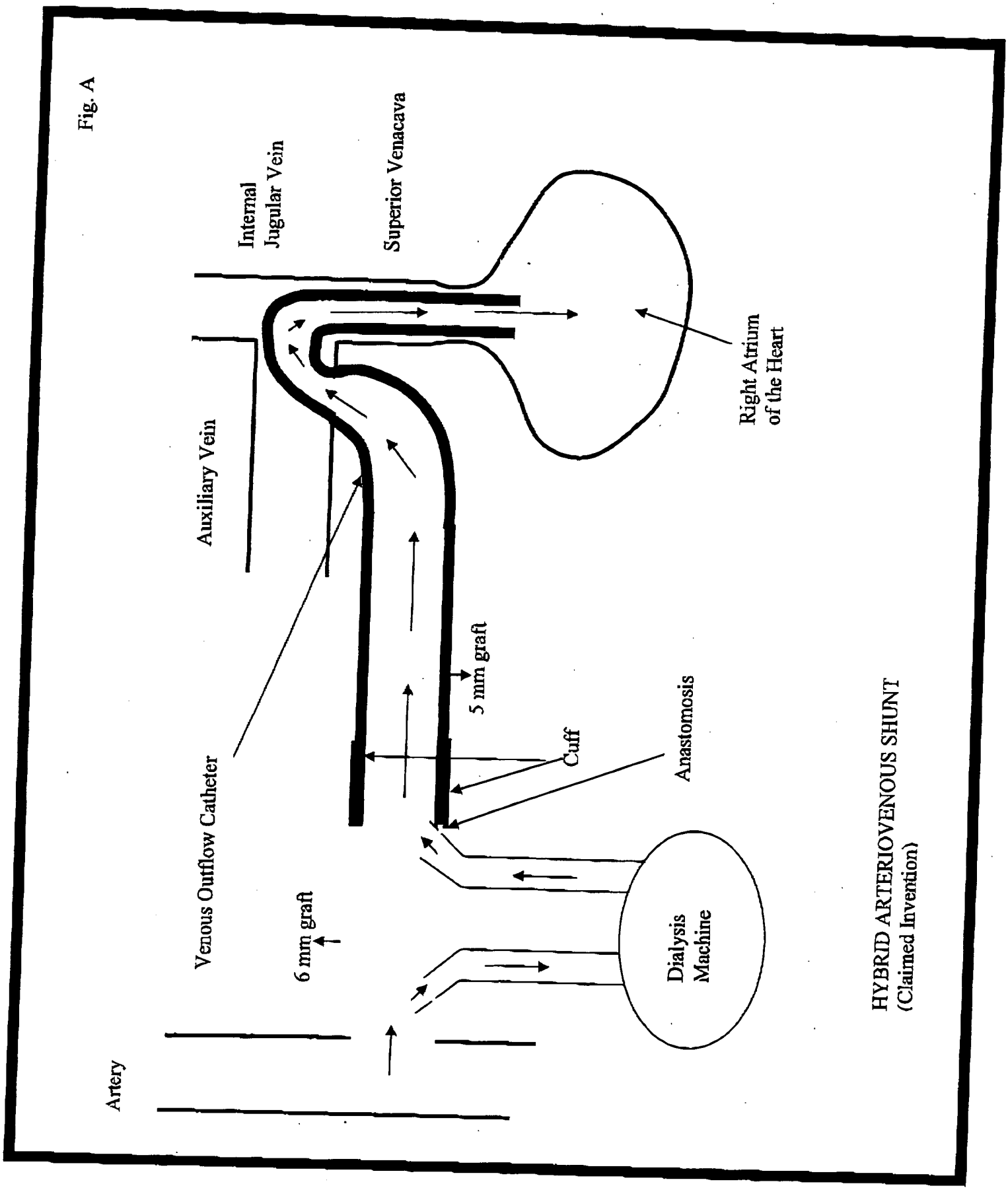

Internal
Jugular Vein
Superior Venacava
Auxiliary Vein
Right Atrium
of the Heart
5 mm graft
Cuff
Anastomosis
Venous Outflow Catheter
6 mm graft
Dialysis
Machine
Artery
HYBRID ARTERIOVENOUS SHUNT
(Claimed Invention)

Fig. B

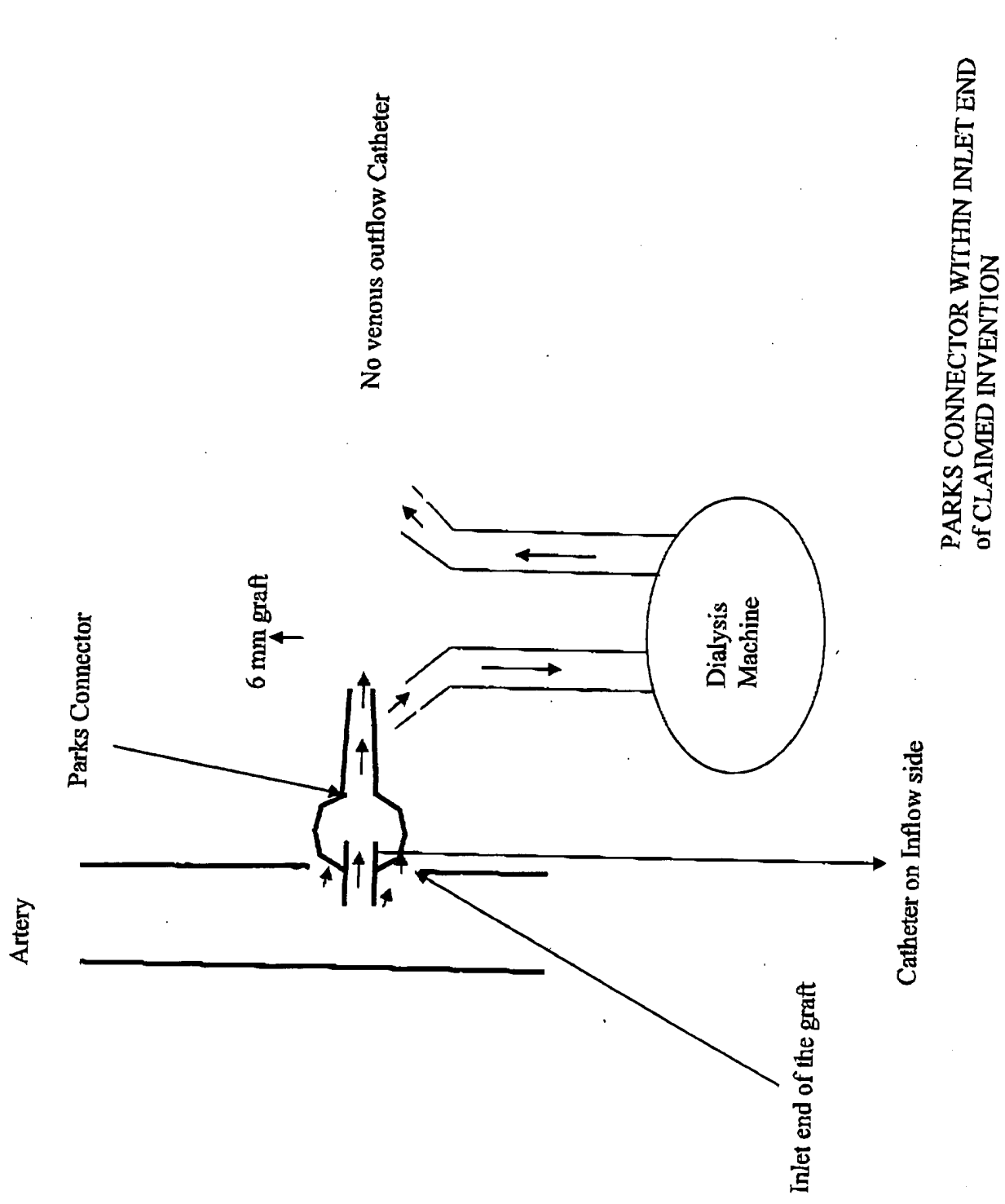
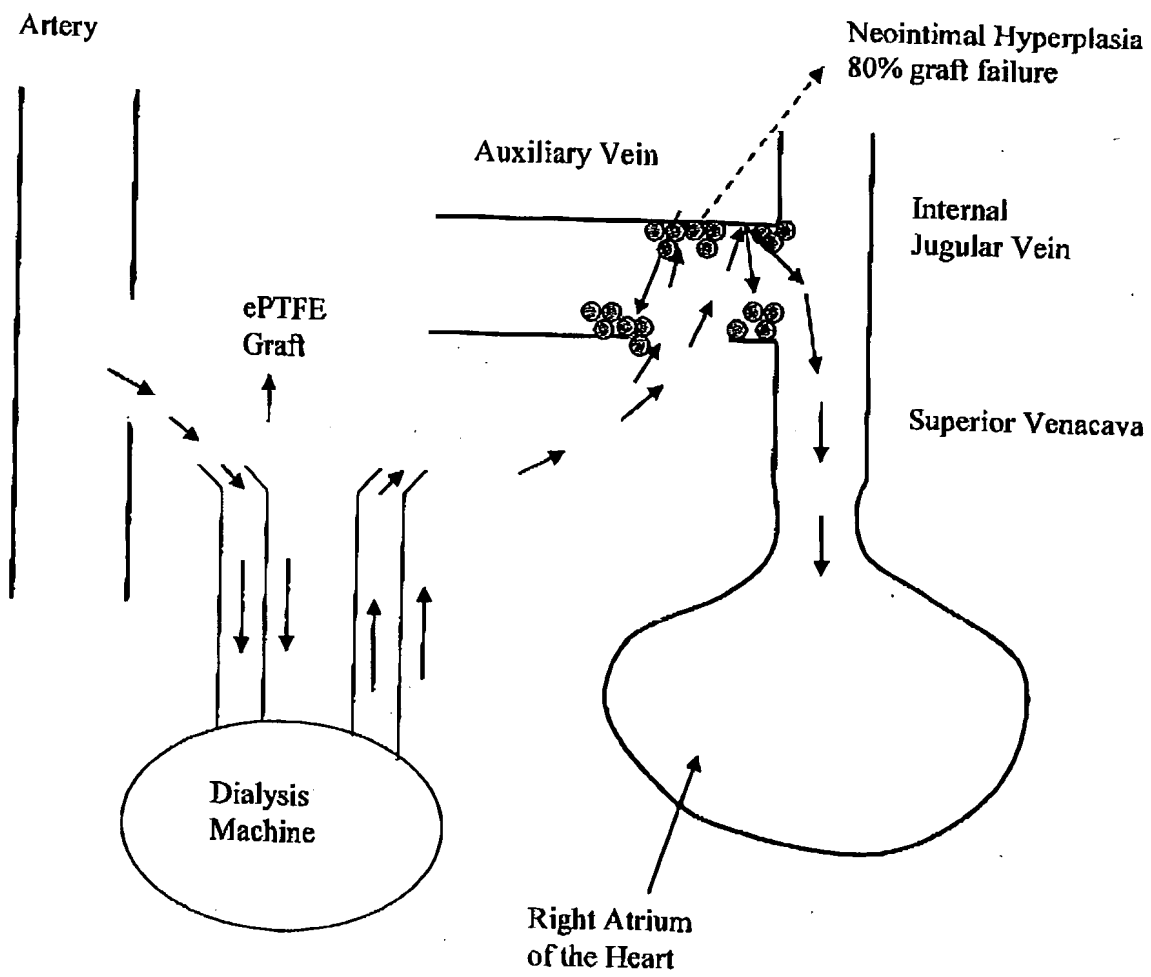

PARKS CONNECTOR WITHIN INLET END
of CLAIMED INVENTION
No venous outflow Catheter
6 mm graft
Parks Connector
Artery
Dialysis
Machine
Catheter on Inflow side
Inlet end of the graft

Fig. C

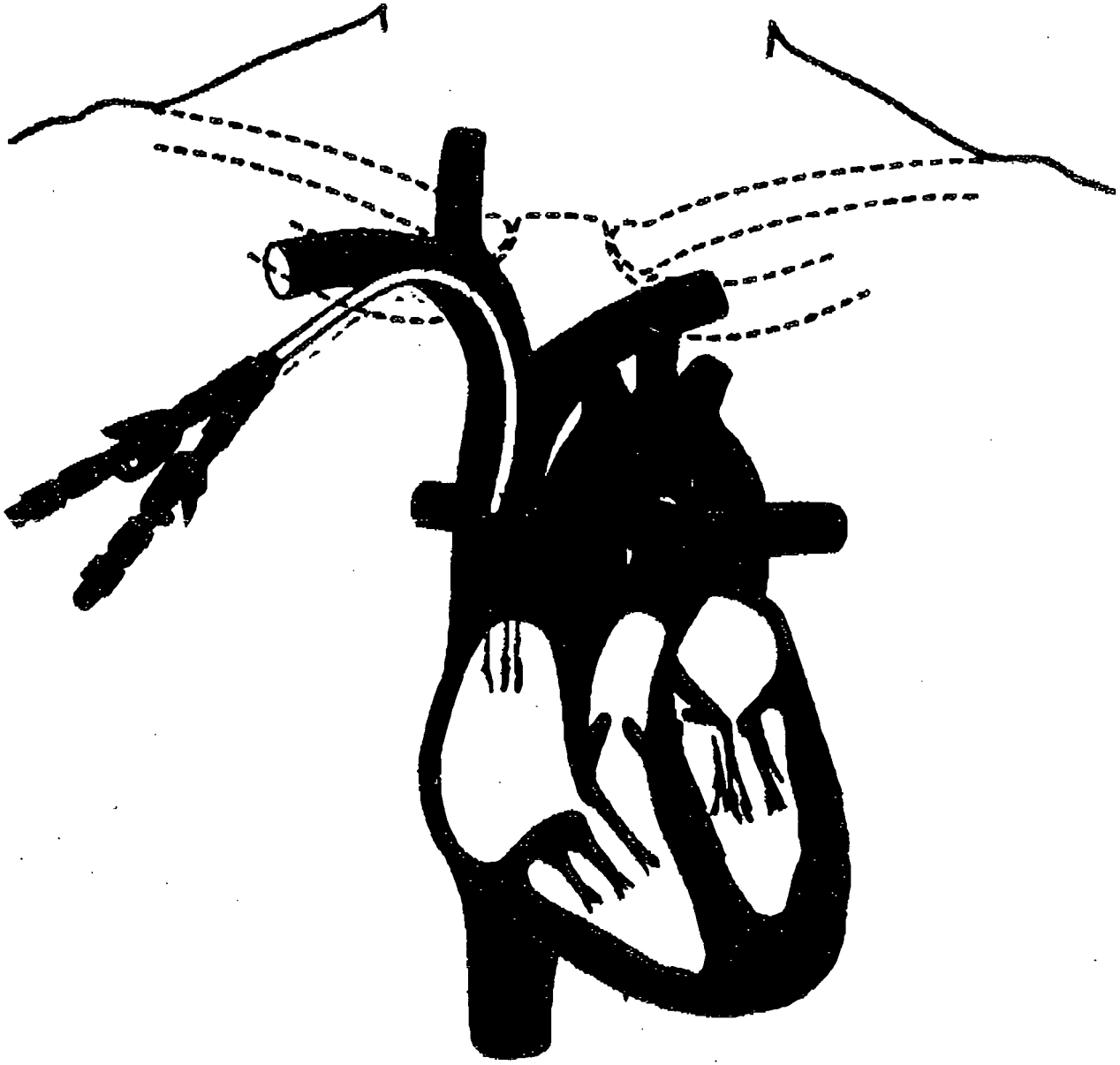


BAKER ARTERIOVENOUS SHUNT – (1976)
Subcutaneous with ePTFE conduit

Showing development of Neointimal Hyperplasia from vein wall injury, due to high pressure blood flow.

Fig:- D

Fig:- D



TUNNELLED DOUBLELUMEN DIALYSIS CATHETER

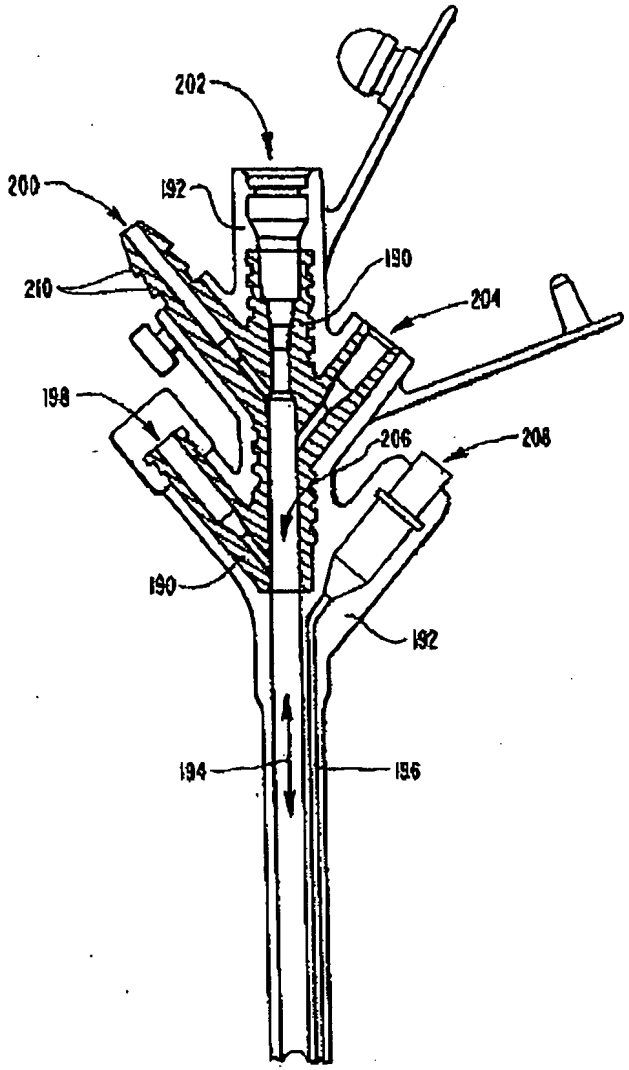


FIG. 12

PARKS CUFF INVENTION

CUFFS:

Non-analagous art related to gastrostomy tube. It has a sloping surface and remains within the gastrostomy tube. This will cause destruction of the function of the A-V shunt of Squitieri and claimed inventions if placed within A-V shunt. Fig. 7, Fig 12.